Utah Department of Health

CLINICAL LABORATORY BULLETIN November 2005

Web page: http://health.utah.gov/lab/labimp

❖ INTRODUCING:

No new lab employees!

NOTEWORTHY

✓ **New web page address:** Please note our web page changed locations. The "els" was replaced with "lab". The correct location is listed above.

✓ **Kudos – Paul Keoppel:** Paul Keoppel, MBA, MT(ASCP) had his picture in CAP Today in an article about keeping medical write-offs to a minimum. Paul is a laboratory compliance / billing administrator for Intermountain Health Care (IHC) in Salt Lake City. He made a presentation on this topic at the July, 2005 AACC national conference.

✓ **Transmitting HBV Through Whole Blood Glucose Monitoring:** The March 11, 2005 MMWR [54(09);220-223] reported on problems with the spread of Hepatitis B (HBV) in patients being monitored for diabetes. Information on Long Term Care Facilities in Mississippi, North Carolina and California were presented.

CDC and FDA recommended in 1990 that facilities restrict blood glucose monitoring devices to individual patient use. The three cases cited in the MMWR indicate these recommendations are not always followed. Suspect transmission causes were identified as using lancets on more than one patient; failure to use gloves – or not changing them after each patient; and using the same spring-loaded, pen-like finger-stick device or the same glucose meter on several patients.

Some patients in the nursing homes died and many others became HBV positive. In one nursing home, the index case was identified, but not in the other two.

✓ **Prevent Lab Errors with a "Read Back" Policy:** If some 70 – 80% of lab errors occur before the test is done, it makes economic sense to prevent as many as possible. It is "Good Laboratory Practice" to take time to repeat verbal information given or taken. Not only can this practice lessen transcription errors, but also help the sender and receiver understand the message correctly. For example, when you call a critical lab value to the clinician, ask the person to repeat the value to ensure correct reporting. When you receive a test order (by phone or in person), repeat the request for clarity. Make certain the other person

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understands you are just trying to be sure correct information is being exchanged. No one should object to efforts at better patient care!

✓ **Botulism: Infant Killer?:** Adults acquire Botulism (the disease) from ingesting preformed toxin. Infants are colonized by *Clostridium botulinum* spores and get the disease when the spores grow vegetative cells which produce the toxin. The Utah Public Health Laboratories (UPHL) tests infants (< 1 year of age) providing they have the symptoms compatible with the disease and the lab receives 10-50 grams of feces (walnut size). The specimen must be kept cool or refrigerated. Do not freeze unless transport will be delayed several days. Frozen samples can be tested for toxin but not cultured. For best results, get the specimen to the lab as soon as possible. To test a person > than 1 year of age, contact Epidemiology at 801-538-6191.

Early symptoms include constipation, lethargy, mild weakness, feeding problems and an altered cry. Later the child becomes "floppy" (loses head control and exhibits generalized, severe muscle weakness).

UPHL does a toxin assay on the feces and then cultures for *Clostridium botulinum.* Positive cultures are typed by injecting a filtrate into live mice. Type A, B, C and E are the most common causes of disease in humans. Toxin A is the most common type in Utah.

Less than 2% of diagnosed infant botulism cases are fatal. There is an effective treatment if administered early in the disease course. Botulism toxin is the most deadly poison known. Risk factors for infant botulism include breastfeeding, dust and that notorious honey. CDC recommends infants not be fed honey.

✓ **New Cardiac Triage Test:** FDA approved the ischemia-modified albumin (IMA) test (manufactured by Inverness Medical Innovations) for a cardiac marker. Most emergency departments, however, don't use it. Just one more expensive test to try to determine who is having a heart attack and who is having indigestion.

The IMA is available on the Beckman Coulter Synchron LX20 and on the Roche/ Hitachi 917 Modular P, 911 and Cobas Mira Plus. In 2006 the company plans to have a point-of-care test ready to market.

Most studies to date show a good negative predictive value for the IMA. Maybe the test will find a niche in cardiac triage and send a few more patients home earlier.

✓ **Validating A New Method:** The finalized CLIA regulations require a laboratory to verify the performance of any non-waived test method "new" to the facility. Before 2003, only highly complex tests needed validation. Like test driving a car before you purchase, you must check the "new" test before you use it for patients. It might be helpful to review the components of a validation.

Accuracy: measures how close the method's result is to the "true" value in the sample you are testing. Is your result correct?
Precision: can you get the same result on the same sample over and over again.
Reportable range: (sometimes called linearity) prove the instrument or method is accurate from the lowest to the highest value it will report. Often your controls or calibrators cover the range the clinician is interested in, but not the full range of the instrument.
Reference interval: (sometimes known as the "normal" range or reference range) assure your patient population fits the manufacturer's definition. When you report a reference range to help clinicians interpret the test result, it may need to be adjusted to your patient's average of ("normal") or for the specific method you use. For example, prothrombin time and PSA results

vary significantly on the same sample by test method – so the reference range must be method specific.

In addition, if you have a "home brew" test or a test not cleared by the FDA, you must validate its sensitivity and specificity. All these validations are done once, before patient testing. Then other quality assessment tools (quality controls, proficiency testing and employee competency) help you assess the test continues to work correctly.

Validation applies to new tests, instruments kits as well as replacement ones. If you plan ahead, you can get the manufacturer to help you with the process – mathematical calculations, reagents, samples that test the method's extremes, etc. Remember every time you get a new brand, non-waived kit (mono or cardiac markers), it must be validated in your lab by your testing personnel before use.

✓ **Rapid Resistant *Staphylococcus aureus* Identification:** PCR is the "gold standard" for detecting methicillin resistant *Staphylococcus aureus* (MRSA). Rapid methods for detection have some drawbacks. If your method is checking for Mec A, realize coagulase negative staphylococci may also have this gene. The identification of the *aureus* species is critical (not all hemolytic, catalase positive, Gram positive cocci are *Staph aureus*). Even if the staphylococcus has the Mec A gene, it may not express the trait the first time you expose it to methicillin.

Pulsed-field gel electrophoresis (PFGE) is accurate but expensive and definitely not rapid (may take up to 5 days). The Evigene MRSA Detection Kit is rapid (3.5 hrs) but cannot detect staphylococci resistant to methicillin by hyper-production of beta-lactamase.

✓ **Proper Specimen Critical for Accurate Test Results:** Pre-analytic errors are the major cause of inaccurate test results. Read the package insert or instrument manual to discover special specimen needs for your method. Especially note requirements for:

- ✓ Patient preparation such as guiaic and urines for culture.
- ✓ Collection containers-urine containers patients bring from home may contain interfering substances.
- ✓ Label – the specimen must contain collection date and time (especially for home collections); patient's full name; and the specimen source (new to the CLIA regulations) when not obvious. Not everything in a plastic, screw-capped container is urine. Pleural fluid can be placed in a vaccutainer for transport.
- ✓ Specimen storage – refrigeration is not good for every test sample.
- ✓ Specimen transport (especially home collected) - samples may need protection from heat, light or cold.
- ✓ Specimen processing – match the specimen to the paper work. If you call the collector to say you have a mis-labeled specimen, they will immediately give you a different label. If you say the specimen and test request don't match, the collector must take responsibility for which is in error.
- ✓ Specimen rejection – don't accept a bad specimen. You will produce bad results that will affect patient care.

You may have the best test in the world and the best personnel in the world performing the test. If you don't have the best specimen, your results could harm rather than help your clients.

✓ **Influenza Again & Again:** An additional influenza vaccine manufacturer received FDA approval this fall. Fluarix, made by Glaxo-SmithKline should help ease vaccine shortages experienced last year. This is the first vaccine released under the FDA's new "fast track" program.

FROM THE PATIENT'S CHART

"The patient was to have a bowel resection. However, he took a job as a stock broker instead."

☆ Feature ☆

Protecting Your Health: Influenza & Avian "Flu"

There have been many health advisories and media reports about the dangers if another world influenza Pandemic, similar to the one in 1918 that killed millions of people, should emerge in the world again. Add to this the concern about "avian influenza" and every one in the healthcare arena must be more vigilant in detecting the emergence of these illnesses in our populations. The following information may help clinical laboratories partner with the Utah Public Health Laboratories (UPHL) and your state and local public health workers to keep Utah's citizens, who include laboratory workers, safe.

Confirm your first positive specimens with viral culture testing:

Confirmatory testing by culture can be done at any viral laboratory that has this technical and safety capability. It is advised that laboratories not try to culture suspected avian influenza samples unless they have BSL3 capability (CDC, 2005). If you already confirm your early season influenza A samples by culture, please continue to do so.

As part of its efforts to watch for the avian influenza or virus strains of influenza that cause symptoms more severe than usual, the UPHL is interested in culture confirming and sub-typing early cases of influenza A (especially for those patients who are hospitalized and have a history of travel to Asia). Ask those with a travel history to Asia if they had physical contact with chickens, geese and/or other fowl. If you suspect your patient has possible avian influenza, UPHL will do sub-typing by PCR, at no charge, to determine if it is the H5N1 strain infecting humans from birds. To see if a patient/specimen qualifies for free testing, please call the Utah Department of Health's Office of Epidemiology at 801-538-6191 and ask to have a case screened for avian influenza.

Caution with the use of rapid test kits to detect influenza:

If your laboratory is using rapid testing for influenza, you may need to collect a second specimen if culture confirmation is to be done (check your kit inserts). There are multiple rapid test kits available for influenza detection making this type of testing widely available. However, the use of these test kits out-of-season or early in the influenza season, when false positives are likely, may lead to unnecessary treatment, modification in vaccination schedules, and inaccurate reports to the media.

The performance characteristics of these tests vary over a broad range, with sensitivity from 57% to 90% and specificity from 65% to 99%. Sensitivity and specificity do not change with the prevalence of influenza disease in your community. **The parameters of clinical relevance to the physician are the predictive value positive** (PVP, the probability that a positive result indicates the presence of disease) and **predictive value negative** (PVN, the probability that a negative result accurately reflects the absence of disease). The **PVP and PVN vary considerably with prevalence.** ***Appropriate use of rapid influenza tests requires an understanding of the influenza***

epidemiology and an understanding of the test performance characteristics.

Influenza A exhibits a pronounced seasonal cycle in Utah. This means the prevalence of the disease may vary from near zero early in the season (October) to peak levels at the height of the outbreak in the community. Although the sensitivity and specificity of a rapid test kit may remain constant, the results are laboratory measures of the reliability of the test when the disease status of the patient is known. The **PVP and PVN** indicate the reliability of the test result for a specific patient whose disease status is unknown. Predictive values are determined by the analytical sensitivity & specificity of the test **AND** the prevalence of the disease in the population tested and will vary during the influenza season.

When using a test with 95% specificity and 95% sensitivity at different times of the year, the likelihood of positive results being accurate could vary from less than 10% (at 1% prevalence) to more than 85% (at 20% prevalence). This points out the importance of doing culture confirmatory testing for influenza, especially early in the season when prevalence is low.

Why partnering with public health is important for Utah and you as a lab worker:

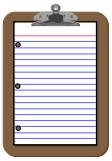
UPHL has the capability of sub-typing influenza A both by staining from confirmatory cultures and by PCR. This allows public health to know if there is a strange or novel sub-type of influenza circulating in the state. It also allows the H5N1 sub-type of avian influenza to be identified. Novel strains and avian influenza might affect your health as a laboratory worker if you worked on a specimen and did not have the appropriate level of personal protective equipment and/or biosafety level containment cabinet to protect yourself from infection. It thus becomes very important for healthcare workers, including laboratorians, to work with public health in identifying influenza cases that could possibly lead to an epidemic.
The Utah Department of Health's Office of Epidemiology posts the latest statistics for influenza in Utah every week at:
http://health.utah.gov/epi/diseases/flu/
If you would like more information on influenza testing at UPHL, please call the laboratory at 801-584-8400 and ask for Tom Sharpton or Barbara Jepson.

References:

Centers for Disease Control and Prevention (CDC). (2005, February 4). Update on avian influenza A (H5N1). Retrieved December 1, 2005, from http://www.cdc.gov/flu/avian/professional/han020405.htm

UPHL is grateful to the Wisconsin State Laboratory of Hygiene for much of the information used in the article. The WSLH website may be accessed from http://www.slh.wisc.edu

Barbara Jepson, MSPH
UPHL Director of Microbiology



CLIA BITS

ADDITIONAL WAIVED TESTS:

° ACON Mononucleosis Rapid Test Strip and Rapid Test Device

° RediScreen Multi-Drug, Multi-Line Screen Test Device

° Accutest Multi-Drug, Multi-Line Screen Device

° Instant Technologies iScreen H. pylori Rapid Test Device and iScreen Mononucleosis Rapid Test Strip and Rapid Test Device

° Polymer Technology Systems CardioChek analyzer and Cardiochek PA Analyzer

° ReliaLAB Inc. InstaRead Lithium System

° Meridian Bioscience ImmunoCare STAT! RSV PLUS

° SA Scientific SAS RSV Test and SAS RSV Alert

° Fisher Scientific Sure-Vue RSV Test

° Remel Xpect RSV

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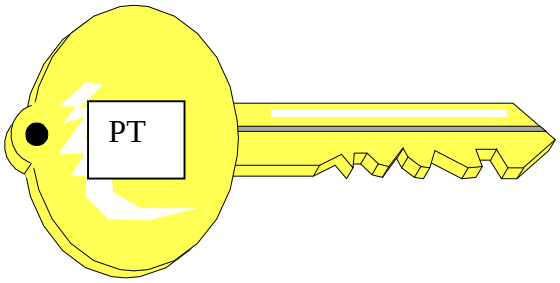
CMS announced in September 2005 persons who have a Doctor of Optometry degree are qualified to be a moderately complex lab director for **test procedures performed in their specialty area**. If their facility performs other moderately complex tests, the Director would need the 20 continuing medical education (CME) credit hours to qualify. Ophthalmologists with a doctor of medicine (MD) are qualified to direct a moderately complex lab as long as they have the requisite one year's experience directing or supervising moderately complex testing.

Equals

"Shortest distance between two jokes: A straight line."



The College of American Pathologists (CAP) was approved August 26, 2005 to provide cytology PAP proficiency testing for 2006. For information on their program go to www.cap.org.

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CAP sent a notice to their subscribers that beginning with the 2006 proficiency testing cycle they will fail any inappropriate antimicrobial / organism results reported on their Bacteriology surveys or EXCEL modules. In the past these incorrect responses were coded "Code 25-Response is not appropriate." Contact CAP if you have questions.

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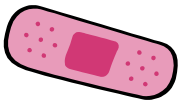
Initial PAP proficiency test results from MIME and the State of Maryland are now on the CLIA website (www.cms.hhs.gov/clia).

Of the 5274 persons tested initially, 4624 passed (88%). The following is a break out of scores by discipline:

Cytotechnologists	= 91% passed
Primary screening MD	= 59% passed
Secondary screening MD	= 87% passed
Locum Tenens	= 63% passed

First Retesting Event (for the 650 who failed the initial test):

Cytotechnologists	= 97% passed
Primary screening MD	= 67% passed
Secondary screening MD	= 87% passed
Locum Tenens	= 100% passed



SAFETY

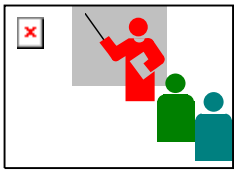
With 4 years experience now applying OSHA's Needlestick Safety and Prevention Act (part of the revised Bloodborne Pathogens Standard in the CFR at 1910.1030), we are still seeing too many needlestick accidents. CDC reports 50% of the needlestick injuries occur after the device is used but before it can be placed in a biohazard container. Most of those accidents occur because of sudden patient movement. Another 10% occur during sharps disposal.

Much of the problem lies with the type (or lack of) safety device used. Don't put yourself or your staff at risk by simply ordering the cheapest device available. OSHA requires staff using the devices to choose the best one for them. Remember the best device won't work unless it is used!

"Courage is fear that said its prayers."

Unknown

CONTINUING EDUCATION



Fellowship Program

The Centers for Disease Control and Prevention (CDC) and the Association of Public Health Laboratories (APHL) offer an Emerging Infectious Diseases (EID) Fellowship Program. The Program prepares laboratory scientists for careers in public health. The two-track program (training and research fellowships) trains qualified candidates (bachelor's and master's level) to support public health initiatives. It also provides opportunities for doctoral level scientists to conduct high priority infectious disease research in public health laboratories. Ideal candidates have laboratory experience (including laboratory coursework) and an interest in public health.

Fellows are placed in local, state, and federal (CDC) public health laboratories. Application deadline is February 17, 2006. For information and an application go online at www.aphl.org/training_and_fellowships/fellowships/.

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University of Iowa Hygienic Laboratory and National Laboratory Training Network (NLTN) Teleconference

CLIA Quality Systems Assessment for Non-waived Laboratories will be presented January 19, 2006 from 11 a.m. to noon MST.

This intermediate level program is appropriate for laboratorians, managers and directors of laboratories performing non-waived tests.

Register at http://www.nltn.org/courses.
Course number = 510-002-06
Registration deadline = January 12, 2006

For questions, call Beth Hochstedler, Iowa State Training Coordinator, at 800-421-4692.

"Experiments never fail."

Dale Dauten